

1 THOMAS C. HORNE
Attorney General
2 (Firm State Bar No. 14000)

3 MONTGOMERY LEE
Assistant Attorney General
4 State Bar No. 005658
1275 W. Washington, CIV/LES
5 Phoenix, Arizona 85007-2997
Tel: (602) 542-7980
6 Fax: (602) 364-3202

7 Attorneys for the Arizona State Board of Pharmacy

8
9 **BEFORE THE ARIZONA STATE BOARD OF PHARMACY**

10 In the Matter of

11 **RX FORMULATIONS**

12 Holder of Pharmacy Permit No. Y003586
13 In the State of Arizona.

Board Case No. 15-0005-PHR

**CONSENT AGREEMENT
FOR STAYED SUSPENSION, CIVIL
PENALTY AND INSPECTIONS**

14
15 In the interest of a prompt and judicious settlement of this case, consistent with the
16 public interest, statutory requirements and the responsibilities of the Arizona State Board
17 of Pharmacy ("Board") under A.R.S. § 32-1901, *et. seq.*, RX Formulations
18 ("Respondent"), holder of Pharmacy Permit No. Y003586 in the State of Arizona and the
19 Board enter into the following Recitals, Findings of Fact, Conclusions of Law and Order
20 ("Consent Agreement") as a final disposition of this matter.

21 **RECITALS**

22 1. Respondent has read and understands this Consent Agreement and has had
23 the opportunity to discuss this Consent Agreement with an attorney, or has waived the
24 opportunity to discuss this Consent Agreement with an attorney.

25

26

1 2. Respondent understands that it has a right to a public administrative hearing
2 concerning this matter at which hearing it could present evidence and cross examine
3 witnesses. By entering into this Consent Agreement, Respondent knowingly and
4 voluntarily relinquishes all right to such an administrative hearing, as well as rights of
5 rehearing, review, reconsideration, appeal, judicial review or any other administrative
6 and/or judicial action, concerning the matters set forth herein.

7 3. Respondent affirmatively agrees that this Consent Agreement shall be
8 irrevocable.

9 4. Respondent understands that this Consent Agreement or any part of the
10 agreement may be considered in any future disciplinary action by the Board against it.

11 5. Respondent understands this Consent Agreement deals with Board
12 Complaint No. 4336 involving allegations of unprofessional conduct against Respondent.
13 The investigation into these allegations against Respondent shall be concluded upon the
14 Board's adoption of this Consent Agreement.

15 6. Respondent understands that this Consent Agreement does not constitute a
16 dismissal or resolution of any other matters currently pending before the Board, if any,
17 and does not constitute any waiver, express or implied, of the Board's statutory authority
18 or jurisdiction regarding any other pending or future investigation, action or proceeding.

19 7. Respondent also understands that acceptance of this Consent Agreement
20 does not preclude any other agency, subdivision, or officer of this State from instituting
21 any other civil or criminal proceedings with respect to the conduct that is the subject of
22 this Consent Agreement.

23 8. Respondent acknowledges and agrees that, upon signing this Consent
24 Agreement and returning this document to the Board's Executive Director, it may not
25 revoke its acceptance of the Consent Agreement or make any modifications to the
26

1 document regardless of whether the Consent Agreement has been signed by the
2 Executive Director. Any modification to this original document is ineffective and void
3 unless mutually agreed by the parties in writing.

4 9. This Consent Agreement is subject to the approval of the Board and is
5 effective only when accepted by the Board and signed by the Executive Director. In the
6 event that the Board does not approve this Consent Agreement, it is withdrawn and shall
7 be of no evidentiary value and shall not be relied upon nor introduced in any action by
8 any party, except that the parties agree that should the Board reject this Consent
9 Agreement and this case proceeds to hearing, Respondent shall assert no claim that the
10 Board was prejudiced by its review and discussion of this document or any records
11 relating thereto.

12 10. If a court of competent jurisdiction rules that any part of this Consent
13 Agreement is void or otherwise unenforceable, the remainder of the Consent Agreement
14 shall remain in full force and effect.

15 11. Respondent understands that this Consent Agreement is a public record that
16 may be publicly disseminated as a formal action of the Board and may be reported as
17 required by law to the National Practitioner Data Bank and the Healthcare Integrity and
18 Protection Data Bank.

19 12. Respondent understands that any violation of this Consent Agreement
20 constitutes unprofessional conduct and may result in disciplinary action. A.R.S. §§ 32-
21 1901.01(B) (20) and A.R.S. § - 1927(A) (1).

22 13. Respondent agrees that the Board will adopt the following Findings of Fact,
23 Conclusions of Law and Order.

24 ...

25 ...

26 ...

1 ACCEPTED AND AGREED BY RESPONDENT

2 Zion's Rx Formulations, LLC.

Dated: 9/16/14

3 By: Troy Albright, member
4 - TROY ALBRIGHT
RX Formulations

5 Subscribed and sworn to before me in the County of MARICOPA, State of ARIZONA
6 this 16TH day of SEPTEMBER, 2014, by RX Formulations.



7 Marsha L. Stolze
8 NOTARY PUBLIC

9 My Commission expires: 3/10/15

10 **FINDINGS OF FACT**

11 1. The Board is the duly constituted authority for licensing and regulating the
12 practice of pharmacy in the State of Arizona.

13 2. Respondent is the holder of permit number Y003586 to operate as a
14 pharmacy in the State of Arizona.

15 3. During all relevant times to these findings, Respondent operated as RX
16 Formulations located at 5949 E. University Drive, Mesa, Arizona.

17 4. On or about November 26, 2013 Pharmacy Board compliance officers
18 received information from Banner Good Samaritan Regional Medical Center Pharmacy
19 ("Banner") regarding possible violations by Respondent relating to the discovery of a
20 contaminated vial of Calcium Gluconate 10% injection which Respondent had prepared
21 and sent to Banner.
22

23 5. On or about November 27, 2013 Pharmacy Board compliance officers
24 began an investigation of the potential violations by Respondent and visited with
25
26

1 representatives of Banner at its facility. During this visit Pharmacy Board compliance
2 officers learned that on November 24, 2013 during the preparation of a sterile order a
3 Banner technician observed a "black blob" inside a syringe of liquid pulled from a
4 Calcium Gluconate 10% PF 100 ml vial Lot #117433@15. The technician alerted the
5 pharmacist on duty who immediately quarantined the Calcium Gluconate 10% 100 ml
6 vial and two drawn up syringes containing the substance. The pharmacist quarantined all
7 Calcium Gluconate 10% inventory within the Banner pharmacy and notified
8 management. Pharmacy Board compliance officers also learned that on November 25,
9 2013 that Banner pharmacy management reviewed purchasing records which revealed
10 that lot numbers 117433@15 and 117466@8 of Calcium Gluconate 10% PF 100 ml
11 product were purchased from Respondent and were contained within the quarantined
12 inventory.

13 6. Later on November 27, 2013 Pharmacy Board compliance officers visited
14 Respondent's facility and interviewed pharmacist-in-charge Troy Albright who admitted
15 at that time that Calcium Gluconate lots prepared by Respondent had not been tested
16 since late April 2013. During this visit Pharmacy Board compliance officers requested
17 that Respondent provide documents including compounding records for lots 117433@15
18 and 117466@8, certificates of analysis form components calcium gluconate powder and
19 calcium saccharate USP tetrahydrate powder, training records for each pharmacy
20 technician, Respondent's most recent media-fill testing results, invoices for each lot,
21 cleaning documentation for hood/cleanroom, policies and procedures, and filter integrity
22 testing results for each lot.

23 7. From December 3, 2013 through December 10, 2013 a Pharmacy Board
24 compliance officer visited Respondent's facility in furtherance of this investigation. On
25 December 3, 2013 a Pharmacy Board compliance officer was accompanied by
26

1 pharmacist-in-charge Troy Albright on a tour of the compounding areas of the facility.
2 During the tour Mr. Albright stated that the garbing was done outside of the anteroom,
3 and then hand washing was done in the anteroom prior to entering the buffer area. Mr.
4 Albright also stated that sterile gloves were then worn prior to entering the hood. Upon
5 entering the buffer area, the Board compliance officer observed gouges in two ceiling
6 tiles and that the ceiling tiles were not caulked. The Board compliance officer also
7 observed that there were gaps for plumbing or wiring in the corners. The Board
8 compliance officer noted that there was no monitoring of pressure differentials between
9 the buffer area and the anteroom.

10 CONCLUSIONS OF LAW

11 1. The Board possesses jurisdiction over the subject matter and over
12 respondent pursuant to A.R.S. § 32-1901 *et seq.*

13 2. The Board may discipline a pharmacy permittee for engaging in
14 unprofessional conduct pursuant to A.R.S. § 32-1927.02 (A) (1).

15 3. The conduct and circumstances described above constitutes unprofessional
16 conduct pursuant to A.R.S. § 32-1901.01(A) (5) (Violating a federal or state law or
17 administrative rule relating to the manufacture, sale or distribution of drugs, devices
18 poisons, hazard substances of precursor chemicals).

19 4. The conduct and circumstances described above constitutes unprofessional
20 conduct in violating A.R.S. § 32-1967 (A) (1) and A.R.S. § 32-1968 (A) (1).

21 4. The conduct and circumstances described above constitutes unprofessional
22 conduct by violating A.A.C. R4-23-410 (A), A.A.C. R4-23-410 (B) (3), A.A.C. R4-23-
23 410 (C) (1), A.A.C. R4-23-410 (I) (2) (b), A.A.C. R4-23-607 (C) (1) and A.A.C. R4-23-
24 607 (C) (3).

1
2 **ORDER**

3 Based upon the above Findings of Fact and Conclusions of Law, IT IS HEREBY
4 ORDERED THAT:

5 1. Respondent's Pharmacy Permit No. Y003586 is hereby suspended for a
6 period of two years upon the adoption of this Consent Agreement by the Board, however,
7 this suspension is stayed pending satisfaction of the terms of this Consent Agreement
8 listed below.

9 2. Respondent shall pay a civil penalty of \$3,000.00 within **180 days** of the
10 effective date of this Order; and

11 3. Respondent shall be subject to two random unannounced inspections by
12 Board staff within one year of the effective date of this Consent Agreement.

13 4. Respondent shall pay all costs associated with complying with this Consent
14 Agreement.

15 5. If Respondent violates this Order in any way, fails to fulfill the
16 requirements of this Order or fails to successfully pass either of the inspections in
17 paragraph 3 of this Order, the Board, after giving the Respondent notice and the
18 opportunity to be heard, may revoke, suspend or take other disciplinary actions against
19 Respondent's license. The issue at such a hearing will be limited solely to whether this
20 Order has been violated.

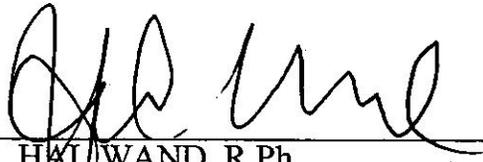
21 6. If Respondent pays the \$3,000.00 civil penalty in paragraph 2 of this Order
22 and successfully passes the inspections in paragraph 3 of this Order it may request in
23 writing that the Board lift the stay of the suspension and vacate the suspension.
24 Respondent's request to terminate the stayed suspension will be considered at a regularly
25
26

1 scheduled Board meeting. Respondent is required to personally appear at that Board
2 meeting.

3 DATED this 24 day of October, 2014.

4
5 (Seal)

ARIZONA STATE BOARD OF PHARMACY

6
7
8 By: 

H. W. WAND, R.Ph.
Executive Director

9
10 ORIGINAL OF THE FORGOING FILED
11 this 24 day of October, 2014, with:

12 Arizona State Board of Pharmacy
13 1616 W. Adams Street
14 Phoenix, Arizona 85007

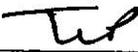
15 EXECUTED COPY OF THE FOREGOING MAILED
16 BY CERTIFIED MAIL
17 this 24 day of October, 2014, to:

18 RX Formulations
19 5949 E. University Drive
20 Mesa, Arizona 85205
21 Respondent

22 Kenneth R. Baker
23 Renaud, Cook, Drury, Mesaros, PA
24 One North Central Avenue, Suite 900
25 Phoenix, Arizona 85004
26 Attorney for Respondent

EXECUTED COPY OF THE FOREGOING MAILED
this 24 day of October, 2014, to:

Montgomery Lee
Assistant Attorney General
1275 W. Washington Street, CIV/LES
Phoenix, Arizona 85007
Attorney for the Board


Doc #4140022